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US-A- 3 122 417
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Description

The invention relates to disinfecting solutions used primarily with contact lenses, especially soft contact lenses, and disinfecting methods employing such solutions.

Hydrogen peroxide solutions have been used for many years for a variety of purposes, including bleaching, disinfecting, and cleaning a variety of surfaces ranging from skin, hair, and mucous membranes to contact lenses to household and industrial surfaces and instruments.

Unfortunately, unless very stringent conditions are met, hydrogen peroxide solutions begin to decompose into oxygen gas and water within an extremely short time. Typical hydrogen peroxide solutions in use for these purposes are in the range of from about 0.5 to about 6 % by weight of hydrogen peroxide in water. The rate at which such dilute hydrogen peroxide solutions decompose will, of course, be dependent upon such factors as pH and the presence of trace amounts of various metal impurities, such as copper or chromium, which may act to catalytically decompose the same. Moreover, at moderately elevated temperatures the rate of decomposition of such dilute aqueous hydrogen peroxide solutions is greatly accelerated. Hence, hydrogen peroxide solutions which have been stabilized against peroxide breakdown are in very great demand.

A large variety of stabilizers has been proposed for use with hydrogen peroxide to deactivate trace catalytic impurities, including stannous salts, ethylene diamine tetracetic acid, and the like.

The primary hydrogen peroxide stabilizer which has been developed and is in wide use today is sodium stannate. This stabilizer serves the desired function of substantially reducing hydrogen peroxide decomposition, and is suitable for a number of applications to which such solutions are put. However, sodium stannate preserved hydrogen peroxide solutions cannot be used with high water content ionic lens materials, since a hazing or milky filming of the lens material results.

In an effort to obtain stabilized peroxide solutions for use with such materials, whether as lenses or other fabricated articles, materials such as Dequest® 2060 (diethylene triamine penta(methylene phosphonic acid, produced by Monsanto) have been used with hydrogen peroxide.

For example, US 3,860,391 discloses bleaching compositions containing hydrogen peroxide and, as a stabilizer, amino lower alkylene polyphosphates, including diethylene triamine penta (methylenephosphonic acid) or salts thereof, and/or hydroxy alkane phosphates, with or without additional stabilizer constituents, and adjusted to a pH of between about 9.0 and 12.0 with, e.g. sodium hydroxide, for the bleaching of cellulose materials. Exemplified are compositions having a pH of 12.0.

While Dequest® 2060 is a good hydrogen peroxide stabilizer, it has been found that its protective action is self limiting. Those stabilizers act by chelating metals, which metals catalyze or enhance the peroxide decomposition. However, this stabilizer undergoes changes in peroxide solutions which make it a poor chelator for metals, and hence, the stabilizing effect is dissipated. It is usually added to the non-peroxide components to chelate peroxide decomposing contaminants before the peroxide is added thereto. If it is added to the peroxide portion, the nitrogens in the Dequest® 2060 become oxidized and the chelating power is lost.

Soft contact lenses are characteristically prepared from hydrophilic polymers, such as polymers of hydroxyethyl methacrylate (HEMA), crosslinked with a conventional crosslinking agent, such as ethylene glycol dimethacrylate (EGDMA), or more complex copolymer systems including copolymers of HEMA, EGDMA, methacrylic acid and/or poly-N-vinylpyrrolidone, and the like. Other hydrophilic monomers conventionally employed in varying amounts in the manufacture of soft contact lenses include, for example, N-vinylpyrrolidone, glyceryl methacrylate, diethylene glycol monomethacrylate, triethylene glycol monomethacrylate, allyl 2-hydroxyethyl ether, acrylic acid, acrylamide, N,N-dimethylacrylamide, and the like. Other conventional crosslinking agents commonly employed include, inter alia, diallyl ether, divinyl benzene, diethylene glycol dimethacrylate, triethylene glycol dimethacrylate, diallyl succinate, allyl methacrylate, glycerin tri-methacrylate, and the like. Moreover, various amounts of relatively hydrophobic monomer units can be employed in the manufacture of soft contact lens materials, as long as the final copolymer network exhibits the desired hydrophilic characteristics. Typical hydrophobic monomers include methyl methacrylate, glycidyl methacrylate, N-(1,1-dimethyl-3-oxobutyl)acrylamide, siloxane methacrylates, perfluoroalkyl methacrylates, perfluoroalkoxyperfluoroalkyl methacrylates, and the like. In general, such lenses exhibit marked hydrophilic properties and, when wet, absorb water and are soft and flexible.

While these lenses are not actually perforate, they do have a sufficient degree of molecular porosity to permit water, oxygen and tear fluids to permeate the lens structure. In order for the disinfection of such lenses to be effective after they have been worn, it is important that contaminants be removed from both surfaces, and the interior of the lens, to the extent contaminants are present therein. Hydrogen peroxide in the form of a dilute solution, e.g. about 0.5 to 6 % by weight in water, is known to be effective for use with contact lenses in order to kill any contaminating microorganisms.

Unfortunately, the highly basic compositions indicated above are undesirable in a contact lens environ-

ment, especially in the disinfection of contact lenses, and in uses of hydrogen peroxide where the composition directly contacts skin, mucous membranes, or instruments made of contact lens polymer materials and subsequently used on or in the body.

The above difficulties and growing importance of peroxide as a disinfectant for contact lens materials makes it imperative that a suitable peroxide stabilizer be found.

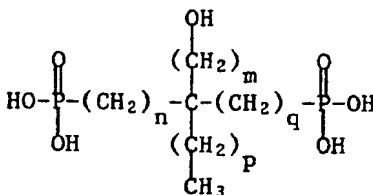
Therefore, one object of this invention is to provide stabilizers for hydrogen peroxide solutions which are compatible with contact lens materials (whether fabricated into contact lenses or other articles) free from the above-mentioned disadvantages.

Another object of the invention is to provide a stabilized hydrogen peroxide solution for use with high water content ionic lens materials.

A further object of the invention is to provide a stabilized hydrogen peroxide solution having a stabilizer which does not tend to lose its stabilizing ability upon exposure to hydrogen peroxide.

A still further object is to provide a method of disinfecting contact lens materials and other articles fabricated from such materials with a stabilized hydrogen peroxide solution.

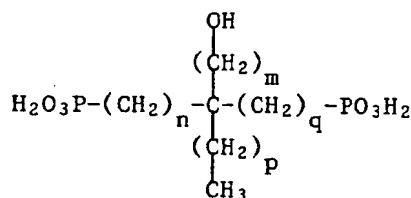
Surprisingly, the foregoing objects and others are achieved by a composition of water, hydrogen peroxide, a primary peroxide stabilizer of the formula



or a physiologically compatible salt thereof and a secondary peroxide stabilizer selected from glycerin, polyvinyl alcohol, propylene glycol, polyacrylic acid, and diethylene glycol.

The instant invention is directed to a hydrogen peroxide disinfecting solution, primarily for disinfecting contact lens materials, especially when such materials are in the form of contact lenses. The invention is of particular importance to the disinfection of high water content, especially ionic, contact lens materials, most importantly to disinfecting such materials having a water content in excess of about 30 %, even more importantly to such materials and especially contact lenses with a water content in the range of about 40 % to about 80 %. The invention is also of great importance regarding disinfection of any lens or lens material which is heat sensitive and therefore cannot be subjected to heat sterilization. Of course, any lens materials (and other materials generally which are stable to hydrogen peroxide) which can be heat treated for disinfection can also be disinfecting with the solution according to the instant invention.

The solution of the invention contains hydrogen peroxide in a concentration which is suitable for disinfecting purposes, preferably about 0.5 % to about 6 %, more preferably about 2 % to about 6 % by weight, most preferably about 3 % by weight. In addition to hydrogen peroxide, the solution contains a primary peroxide stabilizer selected from diphosphonic acid alkanols of the formula



wherein each of n, m, p and q is independently 0-4, or a physiologically compatible salt thereof, in an amount of from about 0.024 mmole to about 0.49 mmole/100 ml of solution; and

a second peroxide stabilizer selected from glycerin, a water soluble polyvinyl alcohol having a molecular weight of about 5,000 to about 150,000 and being at least 80% hydrolyzed, propylene glycol, polyacrylic acid having a molecular weight of about 2,000 to about 100,000, and diethylene glycol, in an amount of from about 0.054 mmole to about 1.09 mmole/100 ml of solution; hydrogen peroxide in a disinfectantly effective amount; and water

In those compounds each of n, m, p and q is independently preferably 0 or 1, most preferably 0. The compound wherein each n, m, p and q is zero is manufactured by Monsanto under the name Dequest® 2010.

The primary stabilizer is present per 100 ml of solution in an amount of at least about 0.024 mmole (50 ppm), preferably 0.039 mmole (80 ppm) up to about 0.34 mmole (700 ppm), more preferably 0.049 mmole (100 ppm) up to about 0.29 mmole (600 ppm), most preferably 0.073 mmole (150 ppm) up to about 0.19 mmole (400 ppm). The amounts in parentheses are for Dequest® 2010 which has a molecular weight of 206. Other primary stabilizers should be present in molar equivalents thereto.

The secondary stabilizer is present in an amount of at least 0.054 mmole (50 ppm), preferably 0.087 mmole (80 ppm), to about 1.09 mmole (1000 ppm), more preferably from about 0.109 mmole (100 ppm) to about 0.87 mmole (800 ppm), most preferably from about 0.22 mmole (200 ppm) to about 0.65 mmole (600 ppm). The quantities in parentheses apply to glycerin (molecular weight = 92); when other secondary stabilizers are used, approximately equimolar amounts thereto are indicated.

The pH of the solution can vary over a wide range but preferably is between about 5.5 and 8.0, more preferably between about 6.0 and about 7.5, still more preferably between about 6.2 and about 7.4. The pH may be adjusted within these bounds, if desired, by any conventional ocularly acceptable buffering system or compound.

Physiologically compatible salts of the diphosphonic acid alkanols include, for example, water soluble salts with conventional pharmaceutically acceptable cationic moieties, including the alkali metal, alkaline earth metal, ammonium and amine cations. Suitable amine salts include, for example, mono-, di- and tri-lower alkyl amines, such as methylamine, ethylamine, diethylamine, triethylamine, dimethylamine, trimethylamine, propylamine, and the like; and mono-, di- and tri-lower hydroxyalkyl amines, such as ethanolamine, diethanolamine, triethanolamine, glucamine, 2-hydroxypropylamine, and the like.

By "lower" in the context of an alkyl group is meant a group having up to 6 carbon atoms, preferably up to 4 carbon atoms.

If desired, additional conventional stabilizers may be employed in conjunction with the primary and secondary stabilizers mentioned above, provided that they do not suffer from the "clouding or filming" defect mentioned above. Hence, stannate stabilizers are specifically excluded from formulations which would be used to disinfect polymer materials typically found in contact lenses.

However, where the material to be disinfected is not adversely affected by stannate stabilizers, the stannates can be added if desired.

Suitable conventional stabilizers include: water soluble stannates (in accordance with the above proviso), such as an alkali metal or ammonium stannate, for example sodium stannate, a water soluble phosphate, polyphosphate or metaphosphate salt, such as an alkali metal or ammonium salt thereof, for example diethylene triamine penta(methylenephosphonic acid); or an amino polycarboxylic acid chelating agent, such as ethylene diamine tetraacetic acid, nitrilo triacetic acid or a water soluble salt thereof, such as an alkali metal or ammonium salt, especially the sodium salt, or mixtures thereof. Where such additional stabilizers are employed, they are generally employed in a physiologically tolerable amount, e.g. in an amount of about 0.002 to about 0.1% by weight.

If desired, ophthalmologically acceptable salts can be present to increase the solution tonicity. Preferably, the solution tonicity is between 390 milliosmole and about 1700 milliosmole, more preferably from about 420 to about 1350 milliosmole, most preferably 420 to about 1320 milliosmole before decomposition of the peroxide, and preferably approximately 250 milliosmole to 350 milliosmole after the peroxide is decomposed. Suitable tonicity enhancing agents include, for example, alkali metal halides, phosphates, hydrogen phosphates, and borates. Preferred are sodium chloride, sodium phosphate monobasic and sodium phosphate dibasic. The function of such tonicity enhancing agents is to increase the comfort level of the solution after decomposition of the hydrogen peroxide in case that subsequent to contact lens disinfection, small amounts of the solution which may adhere to the contact lens, are transferred in the eye of the patient.

Preferably sufficient tonicity enhancing agents are present in the solution, such that upon decomposition of the hydrogen peroxide therein, the resulting solution is substantially isotonic, e.g. substantially equivalent to a 0.9 % by weight aqueous sodium chloride solution.

A further optional ingredient is a thickener or viscosity enhancing agent. Any of the substances known in these categories which are ocularly acceptable can be used. Typical suitable thickeners include, inter alia, polyvinylalcohol, hydroxy ethylcellulose, etc. Thickeners may be present in any amount up to an amount sufficient to raise the overall solution viscosity to about 1000 cps, preferably to not more than 100 cps.

If desired, an additional ocularly acceptable disinfecting agent may be present to enhance the spectrum of the hydrogen peroxide solution disinfection properties. Such additional disinfecting agent may be present in any quantity which will not adversely affect the other components. If present, it is preferably in an amount at which it is disinfectively active up to about 2000 ppm; more preferably from about 10 ppm to about 1000 ppm.

In all cases above, ocularly acceptable materials have been indicated for use in the stabilized hydrogen peroxide solution used to disinfect contact lens materials. This is more of a safety factor than a requirement. Since the hydrogen peroxide in the solution must or should be purged from the disinfected lens and if rinsing is the mode of removal, it is possible, but not recommended, to use ocularly unacceptable components provided that rinsing will remove any residue of such component from the lens.

Furthermore, when the invention solution is being used to disinfect contact lens materials which have been fabricated into articles other than contact lenses, or when the hydrogen peroxide solution is used for bleaching purposes or photographic applications, an even greater range of the optional solution components than set out above can be used.

For example, if compatible with the elements and purpose for which the stabilized hydrogen peroxide solution is being used, one or more of the components may remain on or in the polymer network of the article which component would be incompatible with ocular environment. The scope of such additives for these applications of the stabilized hydrogen peroxide solution will be apparent to those of ordinary skill in the art for which the solution is being applied.

Formulation of the solutions of the invention can be made in any conventional manner. For example, all of the components other than the hydrogen peroxide and water can be placed in a container and fresh, preferably concentrated, e.g. 30 %, hydrogen peroxide added thereto with mixing. Alternatively the dry components can be rubbed up with a small portion of liquid secondary stabilizer, then the remainder of the secondary stabilizer added, followed by the hydrogen peroxide, and most of the water. The viscosity enhancing agent, i.e. thickener, can then be added or the formed solution can be added to the thickener. One of ordinary skill in the art will be aware of numerous variations in the manner of formulating the solutions of the invention.

Contact lenses are disinfected according to the present invention by immersing the lens in the solution. The lens should remain in the solution for a period of not less than about 10 minutes, preferably from about 20 minutes to about 60 minutes. If the lens material is resistant to or stable against heat treatment, both heat and peroxide disinfection can be used. If both are utilized, the time that the lens material must be in the solution of the invention can be decreased, but if both disinfection treatments are needed, the lens material should preferably remain in the solution for no less than 10 minutes.

After the lens material has been immersed in the inventive solution for an appropriate period, the hydrogen peroxide must be removed (if a contact lens is being disinfected). Other medicinal and non medicinal uses of the material being disinfected may or may not require this step. Persons of ordinary skill in the relevant art will be aware if this step is necessary or desirable. When it is desirable to "neutralize" the peroxide activity, any means known, such as rinsing, contacting the solution with platinum, catalase, or any other substance known to decompose hydrogen peroxide, will suffice. When contact lens disinfection is involved the peroxide neutralizer should be completely removable by rinsing or be physiologically compatible. Additional physiological compatible peroxide neutralizing agents include reducing agents such as pyruvic acid and suitable salts thereof such as the sodium salt.

It should be apparent that the instant solutions stabilize hydrogen peroxide and therefore will find additional utility in any application to which hydrogen peroxide may be put. Hence, while one of the primary utilities is disinfection of contact lens materials, the full scope of the invention is the full scope of hydrogen peroxide utility.

Having fully described the invention, the following examples, which do not limit the invention, are presented for a better understanding thereof.

Example 1:

0.010 g of glycerin are dissolved in 80 ml of purified deionized water having a conductivity of 0.5 μ S (micro-Siemens) to which 10 ml of Fisher Chemical pure grade 30 % hydrogen peroxide is added. Purified deionized water (conductivity 0.5 μ S) is added to bring the solution to a volume of 100 ml. The pH is adjusted to 6.5 by hydrogen chloride or sodium hydroxide depending on how long ago the solution has been prepared. Hot stability of this solution is over 95 %. This solution is not suitable to disinfect all types of soft contact lens and rigid gas permeable contact lens polymers.

Hot stability is calculated as:

$$\frac{\text{H}_2\text{O}_2 \text{ present after heating} \cdot 100}{\text{H}_2\text{O}_2 \text{ present before heating}} [\%]$$

In this test the peroxide solution is heated to 100°C for a period of 24 hours. After returning to the preheating temperature the "after heating" peroxide amount is measured.

Example 2:

0.8655 g of sodium chloride, 0.0622 g of anhydrous, dibasic sodium phosphate, 0.0072 g of monobasic sodium phosphate monohydrate, 0.020 g of Dequest® 2010, and 0.030 g of glycerin are dissolved in 80 ml of purified deionized water having a conductivity of 0.5 μ S. To this solution is added 10 ml of Fisher Chemical pure grade 30 % hydrogen peroxide. Water is used to bring the solution to 100 ml, and the pH is adjusted to about 6.5 using HCl or NaOH as needed. Hot stability of the formulation is over 95 %. Disinfection of the contact lens polymer materials in example 1 with this solution left no hazy or milky film.

Example 3:

Example 2 is repeated using contaminated deionized water (conductivity 1 μ S). This term is to be understood in that tap water has been purified up to having a conductivity of 1 μ S. The same results as in example 2 are achieved.

Example 4:

Example 3 is repeated using contaminated deionized water having a conductivity of 2 μ S. The same results as in example 3 are achieved.

Example 5:

Example 3 is repeated but omitting the glycerin. Hot stability of the formulation drops to 92 %.

Example 6:

Example 4 is repeated but omitting the glycerin. Hot stability of this formulation drops to 90 %.

Example 7:

Example 2 is repeated using 0.05 g glycerin instead of 0.02 g Dequest® 2010 and 0.03 g glycerin. Hot stability is 85 %.

Example 8:

Example 7 is repeated using contaminated water (conductivity 1.0 μ S). Hot stability is 82 %.

Example 9:

Example 7 is repeated using water with a conductivity of 2.0 μ S. Hot stability is 78 %.

Example 10:

Example 5 is repeated using 0.03 g Dequest® 2010 instead of 0.02 g and using deionized water (conductivity 0.5 μ S). Hot stability is 95 %.

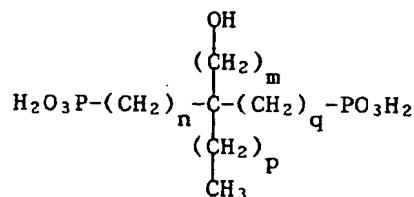
The results of the above examples are summarized in the following tabulation:

Ex.	Dequest® 2010 (g/100 ml)	Glycerin (g/100 ml)	Conductivity of water (µS)	Hot stability
1	-	0.01	0.5	> 95 %
2	0.02	0.03	0.5	> 95 %
3	0.02	0.03	1.0	> 95 %
4	0.02	0.03	2.0	> 95 %
5	0.02	-	1.0	92 %
6	0.02	-	2.0	90 %
7	-	0.05	0.5	85 %
8	-	0.05	1.0	82 %
9	-	0.05	2.0	78 %
10	0.03	-	0.5	95 %

Claims

Claims for the following Contracting States : AT, BE, CH, DE, FR, GB, GR, IT, LI, LU, NL, SE

1. A stabilized hydrogen peroxide solution comprising
a first peroxide stabilizer selected from a compound of the formula



wherein each of n, m, p and q is independently 0-4, or a physiologically compatible salt thereof, in an amount of from about 0.024 mmole to about 0.49 mmole/100 ml of solution; and

a second peroxide stabilizer selected from glycerin, a water soluble polyvinyl alcohol having a molecular weight of about 5,000 to about 150,000 and being at least 80 % hydrolyzed, propylene glycol, polyacrylic acid having a molecular weight of about 2,000 to about 100,000, and diethylene glycol, in an amount of from about 0.054 mmole to about 1.09 mmole/100 ml of solution; hydrogen peroxide in a disinfectantly effective amount; and water.

2. The solution of claim 1 further comprising at least one of

- a) a tertiary hydrogen peroxide stabilizer;
- b) a tonicity builder;
- c) a viscosity enhancer; and
- d) a buffer.

3. The solution of claim 2 wherein said tertiary stabilizer is selected from water soluble stannate, water soluble phosphate, and amino polycarboxylic acid chelating agent; said tonicity builder is selected from alkali metal halides, phosphates, hydrogen phosphates, and borates; said viscosity enhancer is selected from polyvinyl alcohol and hydroxy ethylcellulose; said buffer is selected from alkali metal phosphate, alkali metal borate, and alkali metal pyruvate each alone or in combination with their respective acidic forms.

4. The solution of claim 1 wherein the primary stabilizer is 1,1-diphosphonic acid-ethanol (Dequest® 2010)

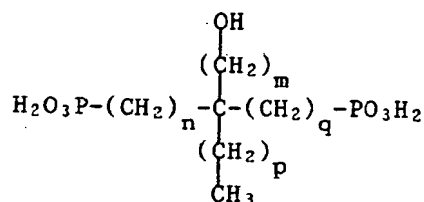
in an amount of about 50 ppm to about 700 ppm based on the entire solution; and the secondary stabilizer is glycerin in an amount of about 50 ppm to about 1000 ppm based on the entire solution.

5. The solution of claim 4 further comprising at least one of

- a) a tertiary hydrogen peroxide stabilizer;
- b) a tonicity builder;
- c) a viscosity enhancer; and
- d) a buffer.

6. The solution of claim 5 wherein said tertiary stabilizer is selected from water soluble stannate, water soluble phosphate, and amino polycarboxylic acid chelating agent; said tonicity builder is selected from alkali metal halides, phosphates, hydrogen phosphates, and borates; said viscosity enhancer is selected from polyvinyl alcohol and hydroxy ethylcellulose; said buffer is selected from alkali metal phosphate, alkali metal borate, and alkali metal pyruvate each alone or in combination with their respective acidic forms.

7. A process for the manufacture of a stabilized hydrogen peroxide solution according to claim 1 comprising mixing a first and second stabilizer with a hydrogen peroxide solution, said first stabilizer being selected from a compound of the formula



wherein each of n, m, p and q is independently 0-4, or from a physiologically compatible salt thereof, in an amount of from about 0.024 mmole to about 0.49 mmole/100 ml of solution; and

said second peroxide stabilizer being selected from glycerin, a water soluble polyvinyl alcohol having a molecular weight of about 5,000 to about 150,000 and being at least 80 % hydrolyzed, propylene glycol, polyacrylic acid having a molecular weight of about 2,000 to about 100,000, and diethylene glycol, in an amount of from about 0.054 mmole to about 1.09 mmole/100 ml of solution.

8. The process of claim 7 further comprising mixing said hydrogen peroxide with at least one additional component selected from

- a) a tertiary hydrogen peroxide stabilizer;
- b) a tonicity builder;
- c) a viscosity enhancer; and
- d) a buffer.

9. The process of claim 8 wherein said tertiary stabilizer is selected from water soluble stannate, water soluble phosphate, and amino polycarboxylic acid chelating agent; said tonicity builder is selected from alkali metal halides, phosphates, hydrogen phosphates, and borates; said viscosity enhancer is selected from polyvinyl alcohol and hydroxy ethylcellulose; said buffer is selected from alkali metal phosphate, alkali metal borate, and alkali metal pyruvate each alone or in combination with their respective acidic forms.

10. A method of disinfecting a hydrogen peroxide stable article comprising contacting said article with a hydrogen peroxide solution of claim 1.

11. The method of claim 10 wherein said article comprises a contact lens polymer material.

12. The method of claim 11 wherein said contact lens polymer material is selected from soft contact lens polymer materials and rigid gas permeable contact polymer materials.

13. The method of claim 11 wherein said article is a contact lens.

14. The method of disinfecting a polymeric contact lens comprising contacting said lens with a stabilized hydrogen peroxide solution according to claim 4.

15. The method of claim 14 using a solution according to claim 5.

16. The method of claim 15 using a solution according to claim 6.

17. The method of claim 14 wherein the pH of said stabilized hydrogen peroxide solution is about 5.5 to about 8.0.

18. The method of claim 14 wherein said stabilized hydrogen peroxide solution has a tonicity of about 390 to about 1350 milliosmoles, before decomposition of said hydrogen peroxide and about 250 milliosmoles to about 350 milliosmoles after said hydrogen peroxide is fully decomposed

19. The method of claim 14 wherein said stabilized hydrogen peroxide solution has a viscosity of up to

1000 cps.

20. The method of claim 14 wherein said contacting step takes place for at least 10 minutes.

21. The method of claim 20 further comprising decomposing said hydrogen peroxide after said contacting step.

5 22. The method of claim 21 wherein said stabilized hydrogen peroxide solution, after said decomposing step is substantially isotonic.

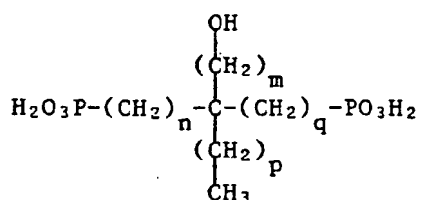
23. The method of claim 21 wherein said decomposing step is carried out with an agent which is compatible with the ocular environment.

10 Claims for the following Contracting State : SP

1. A process for the manufacture of a stabilized hydrogen peroxide solution comprising mixing a first and second stabilizer with a hydrogen peroxide solution, said first stabilizer being selected from a compound of the formula

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25 wherein each of n, m, p and q is independently 0-4, or from a physiologically compatible salt thereof, in an amount of from about 0.024 mmole to about 0.49 mmole/100 ml of solution; and said second peroxide stabilizer being selected from glycerin, a water soluble polyvinyl alcohol having a molecular weight of about 5,000 to about 150,000 and being at least 80 % hydrolyzed, propylene glycol, polyacrylic acid having a molecular weight of about 2,000 to about 100,000, and diethylene glycol, in an amount of from about 0.054 mmole to about 1.09 mmole/100 ml of solution.

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2. The process of claim 1 further comprising mixing said hydrogen peroxide with at least one additional component selected from

a) a tertiary hydrogen peroxide stabilizer;

b) a tonicity builder;

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c) a viscosity enhancer; and

d) a buffer.

3. The process of claim 2 wherein said tertiary stabilizer is selected from water soluble stannate, water soluble phosphate, and amino polycarboxylic acid chelating agent; said tonicity builder is selected from alkali metal halides, phosphates, hydrogen phosphates, and borates; said viscosity enhancer is selected from polyvinyl alcohol and hydroxy ethylcellulose; said buffer is selected from alkali metal phosphate, alkali metal borate, and alkali metal pyruvate each alone or in combination with their respective acidic forms.

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4. The process of claim 1 wherein the primary stabilizer is 1,1-diphosphonic acid-ethanol (Dequest® 2010) in an amount of about 50 ppm to about 700 ppm based on the entire solution; and the secondary stabilizer is glycerin in an amount of about 50 ppm to about 1000 ppm based on the entire solution.

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5. The process of claim 4 further comprising at least one of

a) a tertiary hydrogen peroxide stabilizer;

b) a tonicity builder;

c) a viscosity enhancer; and

d) a buffer.

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6. The process of claim 5 wherein said tertiary stabilizer is selected from water soluble stannate, water soluble phosphate, and amino polycarboxylic acid chelating agent; said tonicity builder is selected from alkali metal halides, phosphates, hydrogen phosphates, and borates; said viscosity enhancer is selected from polyvinyl alcohol and hydroxy ethylcellulose; said buffer is selected from alkali metal phosphate, alkali metal borate, and alkali metal pyruvate each alone or in combination with their respective acidic forms.

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7. A method of disinfecting a hydrogen peroxide stable article comprising contacting said article with a hydrogen peroxide solution the manufacture of which is disclosed in claim 1.

8. The method of claim 7 wherein said article comprises a contact lens polymer material.

9. The method of claim 8 wherein said contact lens polymer material is selected from soft contact lens

polymer materials and rigid gas permeable contact polymer materials.

10. The method of claim 8 wherein said article is a contact lens.

11. The method of disinfecting a polymeric contact lens comprising contacting said lens with a stabilized hydrogen peroxide solution according to claim 4.

5 12. The method of claim 11 using a solution according to claim 5.

13. The method of claim 12 using a solution according to claim 6.

14. The method of claim 11 wherein the pH of said stabilized hydrogen peroxide solution is about 5.5 to about 8.0.

15. The method of claim 11 wherein said stabilized hydrogen peroxide solution has a tonicity of about 390 to about 1350 milliosmoles, before decomposition of said hydrogen peroxide and about 250 milliosmoles to about 350 milliosmoles after said hydrogen peroxide is fully decomposed.

16. The method of claim 11 wherein said stabilized hydrogen peroxide solution has a viscosity of up to 1000 cps.

17. The method of claim 11 wherein said contacting step takes place for at least 10 minutes.

18. The method of claim 17 further comprising decomposing said hydrogen peroxide after said contacting step.

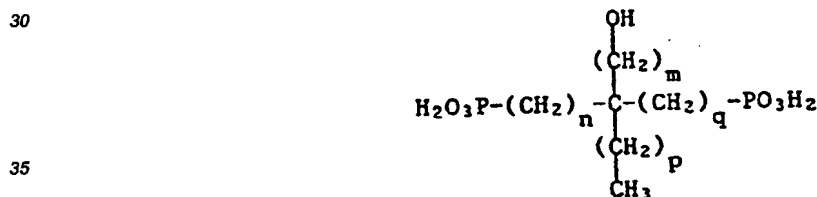
19. The method of claim 18 wherein said stabilizer hydrogen peroxide solution, after said decomposing step is substantially isotonic.

20. The method of claim 18 wherein said decomposing step is carried out with an agent which is compatible with the ocular environment.

Patentansprüche

25 Patentansprüche für folgende Vertragsstaaten : AT, BE, CH, DE, FR, GB, GR, IT, LI, LU, NL, SE

1. Stabilisierte Wasserstoffperoxidlösung, gekennzeichnet durch einen ersten Peroxidstabilisator, ausgewählt aus einer Verbindung der Formel



30 worin n, m, p und q unabhängig voneinander 0 bis 4 bedeuten oder einem physiologisch compablen Salz derselben in einer Menge von ungefähr 0,024 mmol bis ungefähr 0,49 mmol pro 100 ml der Lösung und
 40 einen zweiten Peroxidstabilisator, ausgewählt aus der Gruppe Glycerin, ein wasserlöslicher Polyvinylalkohol mit einem Molekulargewicht von ungefähr 5 000 bis ungefähr 150 000, der zumindestens 80 % hydrolisiert ist, Propylenglycol, Polyacrylsäure mit einem Molekulargewicht von ungefähr 2 000 bis ungefähr 100 000 und Diethylenglycol, in einer Menge von ungefähr 0,054 mmol bis ungefähr 1,09 mmol pro 100 ml der Lösung; Wasserstoffperoxid in einer desinfizierend wirkenden Menge und Wasser.

45 2. Lösung nach Anspruch 1, weiters gekennzeichnet durch mindestens eine der folgenden Komponenten:

- a) ein dritter Wasserstoffperoxidstabilisator
- b) ein die Tonizität aufbauendes Mittel
- c) ein die Viskosität erhöhendes Mittel und
- d) ein Puffer.

50 3. Lösung nach Anspruch 2, worin der genannte dritte Stabilisator ausgewählt ist aus der Gruppe wasserlösliches Stannat, wasserlösliches Phosphat und Aminopolycarbonsäure-Chelatbildner, das genannte die Tonizität aufbauende Mittel ausgewählt ist aus der Gruppe Alkalimetallhalogenide, Phosphate, Hydrogenphosphate und Borate; das die Viskosität erhöhende Mittel ausgewählt ist aus der Gruppe Polyvinylalkohol und Hydroxyethylcellulose; der genannte Puffer ausgewählt ist aus der Gruppe Alkalimetallphosphat, Alkalimetallborat
 55 Alkalimetallpyrovat, jede dieser Verbindungen allein oder in Kombination mit ihren jeweiligen Säure-Formen.

4. Lösung nach Anspruch 1, worin der erste Stabilisator 1,1-Diphosphonsäure-Ethanol (Dequest® 2010) in einer Menge von ungefähr 50 ppm bis ungefähr 700 ppm, bezogen auf die Gesamtlösung und der zweite

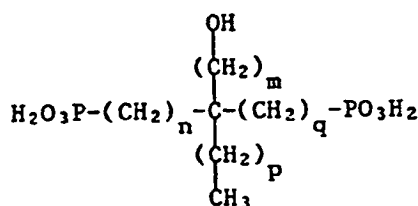
Stabilisator Glycerin in einer Menge von ungefähr 50 ppm bis ungefähr 1 000 ppm, bezogen auf die Gesamtlösung ist.

5. Lösung nach Anspruch 4, weiters gekennzeichnet durch mindestens eine der folgenden Komponenten:

- a) ein dritter Wasserstoffperoxidstabilisator
- b) ein die Tonizität aufbauendes Mittel
- c) ein die Viskosität erhöhendes Mittel und
- d) ein Puffer.

6. Lösung nach Anspruch 5, worin der genannte dritte Stabilisator ausgewählt ist aus der Gruppe wasserlösliches Stannat, wasserlösliches Phosphat und Aminopolycarbonsäure-Chelatbildner, das genannte die Tonizität aufbauende Mittel ausgewählt ist aus der Gruppe Alkalimetallhalogenide, Phosphate, Hydrogenphosphate und Borate; das die Viskosität erhöhende Mittel ausgewählt ist aus der Gruppe Polyvinylalkohol und Hydroxyethylcellulose; der genannte Puffer ausgewählt ist aus der Gruppe Alkalimetallphosphat, Alkalimetallborat und Alkalimetallpyrovat; jede dieser Verbindungen allein oder in Kombination mit ihren jeweiligen Säure-Formen.

7. Verfahren zur Herstellung einer stabilisierten Wasserstoffperoxidlösung gemäß Anspruch 1, dadurch gekennzeichnet, daß ein erster und ein zweiter Stabilisator mit einer Wasserstoffperoxidlösung vermischt wird, wobei der erste Stabilisator ausgewählt ist aus einer Verbindung der Formel



worin n, m, p und q unabhängig voneinander 0 bis 4 bedeuten oder einem physiologisch kompatiblen Salz derselben in einer Menge von ungefähr 0,024 mmol bis ungefähr 0,49 mmol pro 100 ml der Lösung und

einen zweiten Wasserstoffperoxidstabilisator, ausgewählt aus der Gruppe Glycerin, ein wasserlöslicher Polyvinylalkohol mit einem Molekulargewicht von ungefähr 5 000 bis ungefähr 150 000 der zumindestens 80 % hydrolysiert ist, Propylenglycol, Polyacrylsäure mit einem Molekulargewicht von ungefähr 2 000 bis ungefähr 100 000 und Diethylenglycol, in einer Menge von ungefähr 0,054 mmol bis ungefähr 1,09 mmol pro 100 ml der Lösung.

8. Verfahren nach Anspruch 7, weiters gekennzeichnet durch das Vermischen des genannten Wasserstoffperoxids mit zumindest einer zusätzlichen Komponente ausgewählt aus der Gruppe

- a) ein dritter Wasserstoffperoxidstabilisator
- b) ein die Tonizität aufbauendes Mittel
- c) ein die Viskosität erhöhendes Mittel und
- d) ein Puffer.

9. Verfahren nach Anspruch 8, worin der genannte dritte Stabilisator ausgewählt ist aus der Gruppe wasserlösliches Stannat, wasserlösliches Phosphat und Aminopolycarbonsäure-Chelatbildner, das genannte die Tonizität aufbauende Mittel ausgewählt ist aus der Gruppe Alkalimetallhalogenide, Phosphate, Hydrogenphosphate und Borate; das die Viskosität erhöhende Mittel ausgewählt ist aus der Gruppe Polyvinylalkohol und Hydroxyethylcellulose; der genannte Puffer ausgewählt ist aus der Gruppe Alkalimetallphosphat, Alkalimetallborat und Alkalimetallpyrovat; jede dieser Verbindungen allein oder in Kombination mit ihren jeweiligen Säure-Formen.

10. Verfahren zur Desinfektion eines gegenüber Wasserstoffperoxid beständigen Gegenstandes, dadurch gekennzeichnet, daß der genannte Gegenstand mit einer Wasserstoffperoxidlösung gemäß Anspruch 1 in Kontakt gebracht wird.

11. Verfahren nach Anspruch 10, worin der genannte Gegenstand ein Kontaktlinsen-Polymermaterial enthält.

12. Verfahren nach Anspruch 11, worin das genannte Kontaktlinsen-Polymermaterial ausgewählt ist aus der Gruppe Polymermaterialien für weiche Kontaktlinsen und Polymermaterialien für harte gasdurchlässige Kontaktlinsen.

13. Verfahren nach Anspruch 11, worin der genannte Gegenstand eine Kontaktlinse ist.

14. Verfahren zur Desinfektion einer Polymer-Kontaktlinse, dadurch gekennzeichnet, daß die genannte Linse mit einer stabilisierten Wasserstoffperoxidlösung gemäß Anspruch 4 in Kontakt gebracht wird.

15. Verfahren nach Anspruch 14, dadurch gekennzeichnet, daß eine Lösung gemäß Anspruch 5 verwendet wird.

16. Verfahren nach Anspruch 15, dadurch gekennzeichnet, daß eine Lösung gemäß Anspruch 6 verwendet wird.

5 17. Verfahren nach Anspruch 14, worin der pH-Wert der genannten stabilisierten Wasserstoffperoxidlösung ungefähr 5,5 bis ungefähr 8,0 beträgt.

18. Verfahren nach Anspruch 14, worin die genannte stabilisierte Wasserstoffperoxidlösung vor der Zersetzung des Wasserstoffperoxids eine Tonizität von ungefähr 390 bis ungefähr 1350 milliosmol und nachdem das Wasserstoffperoxid vollständig zersetzt ist, eine Tonizität von ungefähr 250 milliosmol bis ungefähr 350 milliosmol aufweist.

19. Verfahren nach Anspruch 14, worin die stabilisierte Wasserstoffperoxidlösung eine Viskosität von bis zu 1000 cps aufweist.

20. Verfahren nach Anspruch 14, worin der Schritt des Inkontaktbringens mindestens 10 Minuten andauert.

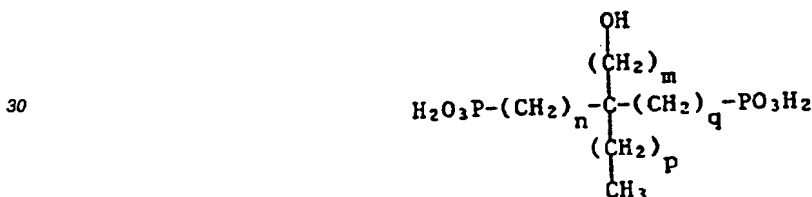
21. Verfahren nach Anspruch 20, weiters dadurch gekennzeichnet, daß das Wasserstoffperoxid nach dem Inkontaktbringen zersetzt wird.

22. Verfahren nach Anspruch 21, dadurch gekennzeichnet, daß die stabilisierte Wasserstoffperoxidlösung nach dem Zersetzungsschritt im wesentlichen isotonisch ist.

23. Verfahren nach Anspruch 21, dadurch gekennzeichnet, daß der Zersetzungsschritt mit einem Mittel ausgeführt wird, welches mit dem Augenmilieu verträglich ist.

20 Patentansprüche für folgenden Vertragsstaat : ES

1. Verfahren zur Herstellung einer stabilisierten Wasserstoffperoxidlösung, dadurch gekennzeichnet, daß ein erster und ein zweiter Stabilisator mit einer Wasserstoffperoxidlösung vermischt wird, wobei der erste Stabilisator ausgewählt ist aus einer Verbindung der Formel



35 worin n, m, p und q unabhängig voneinander 0 bis 4 bedeuten oder einem physiologisch kompatiblen Salz derselben in einer Menge von ungefähr 0,024 mmol bis ungefähr 0,49 mmol pro 100 ml der Lösung und einen zweiten Wasserstoffperoxidstabilisator, ausgewählt aus der Gruppe Glycerin, ein wasserlöslicher Polyvinylalkohol mit einem Molekulargewicht von ungefähr 5 000 bis ungefähr 150 000 der zumindestens 80 % hydrolysiert ist, Propylenglycol, Polyacrylsäure mit einem Molekulargewicht von ungefähr 2 000 bis ungefähr 100 000 und Diethylenglycol, in einer Menge von ungefähr 0,054 mmol bis ungefähr 1,09 mmol pro 100 ml der Lösung.

2. Verfahren nach Anspruch 1, weiters gekennzeichnet durch das Vermischen des genannten Wasserstoffperoxids mit zumindest einer zusätzlichen Komponente ausgewählt aus der Gruppe

- a) ein dritter Wasserstoffperoxidstabilisator
- b) ein die Tonizität aufbauendes Mittel
- c) ein die Viskosität erhöhendes Mittel und
- d) ein Puffer.

3. Verfahren nach Anspruch 2, worin der genannte dritte Stabilisator ausgewählt ist aus der Gruppe wasserlösliches Stannat, wasserlösliches Phosphat und Aminopolycarbonsäure-Chelatbildner; das genannte die Tonizität aufbauende Mittel ausgewählt ist aus der Gruppe Alkalimetallhalogenide, Phosphate, Hydrogenphosphate und Borate; das die Viskosität erhöhende Mittel ausgewählt ist aus der Gruppe Polyvinylalkohol und Hydroxyethylcellulose; der genannte Puffer ausgewählt ist aus der Gruppe Alkalimetallphosphat, Alkalimetallborat und Alkalimetallpyrovat; jede dieser Verbindungen allein oder in Kombination mit ihren jeweiligen Säure-Formen.

4. Verfahren nach Anspruch 1, worin der erste Stabilisator 1,1-Diphosphonsäure-Ethanol (Dequest® 2010) in einer Menge von ungefähr 50 ppm bis ungefähr 700 ppm, bezogen auf die Gesamtlösung und der zweite Stabilisator Glycerin in einer Menge von ungefähr 50 ppm bis ungefähr 1 000 ppm, bezogen auf die Gesamtlösung ist.

5. Verfahren nach Anspruch 4, weiters gekennzeichnet durch mindestens eine der folgenden Komponenten-

ten:

- a) ein dritter Wasserstoffperoxidstabilisator
- b) ein die Tonizität aufbauendes Mittel
- c) ein die Viskosität erhöhendes Mittel und
- d) ein Puffer.

6. Verfahren nach Anspruch 5, worin der genannte dritte Stabilisator ausgewählt ist aus der Gruppe wasserlösliches Stannat, wasserlösliches Phosphat und Aminopolycarbonsäure-Chelatbildner, das genannte die Tonizität aufbauende Mittel ausgewählt ist aus der Gruppe Alkalimetallhalogenide, Phosphate, Hydrogenphosphate und Borate; das die Viskosität erhöhende Mittel ausgewählt ist aus der Gruppe Polyvinylalkohol und Hydroxyethylcellulose; der genannte Puffer ausgewählt ist aus der Gruppe Alkalimetallphosphat, Alkalimetallborat und Alkalimetallpyrovat; jede dieser Verbindungen allein oder in Kombination mit ihren jeweiligen Säure-Formen.

7. Verfahren zur Desinfektion eines gegenüber Wasserstoffperoxid beständigen Gegenstandes, dadurch gekennzeichnet, daß der genannte Gegenstand mit einer Wasserstoffperoxidlösung in Kontakt gebracht wird, deren Herstellung in Anspruch 1 geoffenbart ist.

8. Verfahren nach Anspruch 7, worin der genannte Gegenstand ein Kontaktlinsen-Polymermaterial enthält.

9. Verfahren nach Anspruch 8, worin das genannte Kontaktlinsen-Polymermaterial ausgewählt ist aus der Gruppe Polymermaterialien für weiche Kontaktlinsen und Polymermaterialien für harte gasdurchlässige Kontaktlinsen.

10. Verfahren nach Anspruch 8, worin der genannte Gegenstand eine Kontaktlinse ist.

11. Verfahren zur Desinfektion einer Polymer-Kontaktlinse, dadurch gekennzeichnet, daß die genannte Linse mit einer stabilisierten Wasserstoffperoxidlösung gemäß Anspruch 4 in Kontakt gebracht wird.

12. Verfahren nach Anspruch 11, dadurch gekennzeichnet, daß eine Lösung gemäß Anspruch 5 verwendet wird.

13. Verfahren nach Anspruch 12, dadurch gekennzeichnet, daß eine Lösung gemäß Anspruch 6 verwendet wird.

14. Verfahren nach Anspruch 11, worin der pH-Wert der genannten stabilisierten Wasserstoffperoxidlösung ungefähr 5,5 bis ungefähr 8,0 beträgt.

15. Verfahren nach Anspruch 11, worin die genannte stabilisierte Wasserstoffperoxidlösung vor der Zersetzung des Wasserstoffperoxids eine Tonizität von ungefähr 390 bis ungefähr 1350 milliosmol und nachdem das Wasserstoffperoxid vollständig zersetzt ist, eine Tonizität von ungefähr 250 milliosmol bis ungefähr 350 milliosmol aufweist.

16. Verfahren nach Anspruch 11, worin die stabilisierte Wasserstoffperoxidlösung eine Viskosität von bis zu 1000 cps aufweist.

17. Verfahren nach Anspruch 11, worin der Schritt des Inkontaktbringens mindestens 10 Minuten andauert.

18. Verfahren nach Anspruch 17, weiters dadurch gekennzeichnet, daß das Wasserstoffperoxid nach dem Inkontaktbringen zersetzt wird.

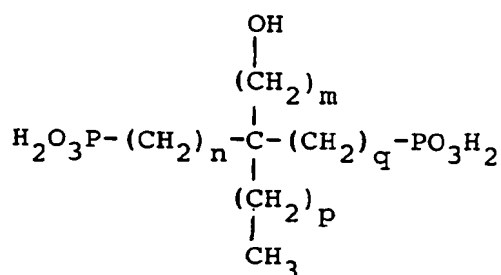
19. Verfahren nach Anspruch 18, dadurch gekennzeichnet, daß die stabilisierte Wasserstoffperoxidlösung nach dem Zersetzungsschritt im wesentlichen isotonisch ist.

20. Verfahren nach Anspruch 18, dadurch gekennzeichnet, daß der Zersetzungsschritt mit einem Mittel ausgeführt wird, welches mit dem Augenmilieu verträglich ist.

Revendications

Revendications pour les Etats contractants suivants: AT, BE, CH, DE, FR, GB, GR, IT, LI, LU, NL, SE

1. Une solution de peroxyde d'hydrogène stabilisée comprenant un premier stabilisant du peroxyde, choisi parmi les composés de formule



dans laquelle chacun des symboles n, m, p et q est, indépendamment des autres, un nombre de 0 à 4, ou leurs sels acceptables pour l'usage pharmaceutique, en proportions d'environ 0,024 mmol à environ 0,49 mmol pour 100 ml de la solution; et

un second stabilisant du peroxyde choisi parmi le glycérol, un alcool polyvinylique soluble dans l'eau de poids moléculaire 5 000 à 150 000 environ et hydrolysé à au moins 80 %, le propylène-glycol, un acide polyacrylique de poids moléculaire 2 000 à 100 000 environ et le diéthylène-glycol, en proportions d'environ 0,054 mmol à environ 1,09 mmol pour 100 ml de la solution; du peroxyde d'hydrogène en proportions efficaces pour la désinfection; et de l'eau.

2. La solution de la revendication 1, comprenant en outre au moins un des composants suivants :

- a) un stabilisant tertiaire du peroxyde d'hydrogène;
- b) un agent de tonicité;
- c) un agent accroissant la viscosité; et
- d) un tampon.

3. La solution de la revendication 2, dans laquelle le stabilisant tertiaire est choisi parmi les stannates solubles dans l'eau, les phosphates solubles dans l'eau et les agents séquestrants du type acide aminopolycarboxylique; l'agent de tonicité est choisi parmi les halogénures, les phosphates, les hydrogénophosphates et les borates de métaux alcalins; l'agent accroissant la viscosité est choisi parmi l'alcool polyvinylique et l'hydroxyéthylcellulose; le tampon est choisi parmi les phosphates de métaux alcalins, les borates de métaux alcalins et les pyruvates de métaux alcalins, isolément ou en combinaison avec leurs acides respectifs.

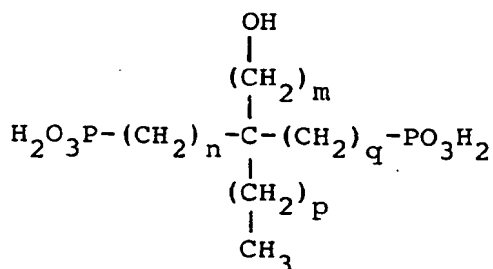
4. La solution de la revendication 1, dans laquelle le stabilisant primaire est l'acide éthanol-1,1-diphosphonique (produit du commerce Dequest 2010) en proportions d'environ 50 à 700 ppm de la solution totale; et le stabilisant secondaire est le glycérol, en proportions d'environ 50 à 1 000 ppm de la solution totale.

5. La solution de la revendication 4, comprenant en outre au moins un des composants suivants :

- a) un stabilisant tertiaire du peroxyde d'hydrogène;
- b) un agent de tonicité;
- c) un agent accroissant la viscosité; et
- d) un tampon.

6. La solution de la revendication 5, dans laquelle le stabilisant tertiaire est choisi parmi les stannates solubles dans l'eau, les phosphates solubles dans l'eau et les agents séquestrants du type acide aminopolycarboxylique; l'agent de tonicité est choisi parmi les halogénures, les phosphates, les hydrogénophosphates et les borates de métaux alcalins; l'agent accroissant la viscosité est choisi parmi l'alcool polyvinylique et l'hydroxyéthylcellulose; le tampon est choisi parmi les phosphates de métaux alcalins et les borates de métaux alcalins et les pyruvates de métaux alcalins, isolément ou en combinaison avec leurs acides respectifs.

7. Un procédé de préparation d'une solution de peroxyde d'hydrogène stabilisée selon la revendication 1, qui consiste à mélanger un premier et un second stabilisants avec une solution de peroxyde d'hydrogène, ce premier stabilisant étant choisi parmi les composés de formule



dans laquelle chacun des symboles n, m, p et q est, indépendamment des autres, un nombre de 0 à 4, ou parmi leurs sels acceptables pour l'usage pharmaceutique, en proportions d'environ 0,024 mmol à environ 0,49 mmol pour 100 ml de la solution; et le second stabilisant du peroxyde est choisi parmi le glycérol, un alcool polyvinylique soluble dans l'eau de poids moléculaire environ 5 000 à 150 000 et hydrolysé à au moins 80 %, le propylène-glycol, un acide polyacrylique de poids moléculaire 2 000 à 100 000 environ et le diéthylène-glycol, en proportions d'environ 0,054 mmol à 1,09 mmol pour 100 ml de la solution.

8. Le procédé de la revendication 7, consistant en outre à mélanger le peroxyde d'hydrogène avec au moins un autre composant choisi parmi

- a) un stabilisant tertiaire du peroxyde d'hydrogène;
- b) un agent de tonicité;
- c) un agent accroissant la viscosité; et
- d) un tampon.

9. Le procédé de la revendication 8, dans lequel le stabilisant tertiaire est choisi parmi les stannates solubles dans l'eau, les phosphates solubles dans l'eau et les agents séquestrants du type acide aminopolycarboxylique; l'agent de tonicité est choisi parmi les halogénures, les phosphates, les hydrogénophosphates, les borates de métaux alcalins; l'agent accroissant la viscosité est choisi parmi l'alcool polyvinylique et l'hydroxyéthylcellulose; le tampon est choisi parmi les phosphates de métaux alcalins, les borates de métaux alcalins et les pyruvates de métaux alcalins, isolément ou en combinaison avec leurs acides respectifs.

10. Un procédé pour désinfecter un article stable au peroxyde d'hydrogène, qui consiste à mettre cet article en contact avec une solution de peroxyde d'hydrogène de la revendication 1.

11. Le procédé de la revendication 10, dans lequel cet article consiste en une matière polymère pour lentilles de contact.

12. Le procédé de la revendication 11, dans lequel la matière polymère pour lentilles de contact est choisi parmi les matières polymères pour lentilles de contact molles et les matières polymères perméables aux gaz pour lentilles de contact rigides.

13. Le procédé de la revendication 11, dans lequel l'article est une lentille de contact.

14. Le procédé de désinfection d'une lentille de contact polymère consistant à mettre cette lentille en contact avec une solution de peroxyde d'hydrogène stabilisée selon la revendication 4.

15. Le procédé de la revendication 14, utilisant une solution selon la revendication 5.

16. Le procédé de la revendication 15, utilisant une solution selon la revendication 6.

17. Le procédé de la revendication 14, dans lequel le pH de la solution de peroxyde d'hydrogène stabilisée est d'environ 5,5 à 8,0.

18. Le procédé de la revendication 14 dans lequel la solution de peroxyde d'hydrogène stabilisée a une tonicité d'environ 390 à 1350 milliosmoles avant décomposition du peroxyde d'hydrogène et d'environ 250 à 350 milliosmoles après décomposition complète du peroxyde d'hydrogène.

19. Le procédé de la revendication 14, dans lequel la solution de peroxyde d'hydrogène stabilisée a une viscosité allant jusqu'à 1000 cps.

20. Le procédé de la revendication 14, dans lequel le contact dure pendant au moins 10 minutes.

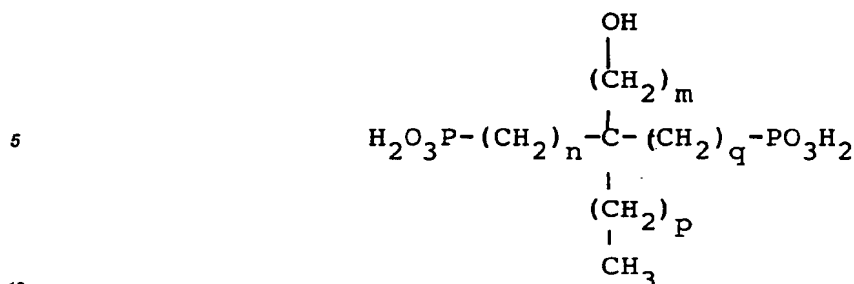
21. Le procédé de la revendication 20, comprenant en outre la décomposition du peroxyde d'hydrogène après le contact.

22. Le procédé de la revendication 21, dans lequel la solution de peroxyde d'hydrogène stabilisée, après la décomposition du peroxyde d'hydrogène, est pratiquement isotonique.

23. Le procédé de la revendication 21, dans lequel la décomposition est provoquée par un agent acceptable pour l'usage ophtalmologique.

Revendications pour l'Etat contractant suivant : ES

1. Un procédé de préparation d'une solution de peroxyde d'hydrogène stabilisée, consistant à mélanger un premier et un second stabilisant avec une solution de peroxyde d'hydrogène, le premier stabilisant étant choisi parmi les composés de formule



dans laquelle chacun des symboles n, m, p et q est, indépendamment des autres, un nombre de 0 à 4, ou leurs sels acceptables pour l'usage pharmaceutique, en proportions d'environ 0,024 mmol à environ 0,49 mmol pour 100 ml de la solution; et le second stabilisant du peroxyde est choisi parmi le glycérol, un alcool polyvinylique soluble dans l'eau de poids moléculaire 5 000 à 150 000 environ et hydrolysé à au moins 80 %, le propylène-glycol, un acide polyacrylique de poids moléculaire 2 000 à 100 000 environ et le diéthylène-glycol, en proportions d'environ 0,054 mmol à environ 1,09 mmol pour 100 ml de la solution.

2. Le procédé de la revendication 1, consistant en outre à mélanger ce peroxyde d'hydrogène avec au moins un autre composant choisi parmi les suivants :

- a) un stabilisant tertiaire du peroxyde d'hydrogène;
- b) un agent de tonicité;
- c) un agent accroissant la viscosité; et
- d) un tampon.

3. Le procédé de la revendication 2, dans lequel le stabilisant tertiaire est choisi parmi les stannates solubles dans l'eau, les phosphates solubles dans l'eau et les agents séquestrants du type acide aminopolycarboxylique; l'agent de tonicité est choisi parmi les halogénures, les phosphates, les hydrogénéo-phosphates et les borates de métaux alcalins; l'agent accroissant la viscosité est choisi parmi l'alcool polyvinylique et l'hydroxyéthylcellulose; le tampon est choisi parmi les phosphates de métaux alcalins, les borates de métaux alcalins et les pyruvates de métaux alcalins, isolément ou en combinaison avec leurs acides respectifs.

4. Le procédé de la revendication 1 dans lequel le stabilisant primaire est l'acide éthanol-1,1-diphosphonique (produit du commerce Dequest 2010) en proportions d'environ 50 ppm à environ 700 ppm, par rapport à la solution totale; et le stabilisant secondaire est le glycérol, en proportions d'environ 50 ppm à environ 1 000 ppm, par rapport à la solution totale.

5. Le procédé de la revendication 5, comprenant en outre au moins un composant choisi parmi les suivants:

- a) un stabilisant tertiaire du peroxyde d'hydrogène;
- b) un agent de tonicité;
- c) un agent accroissant la viscosité; et
- d) un tampon.

6. Le procédé de la revendication 5 dans lequel le stabilisant tertiaire est choisi parmi les stannates solubles dans l'eau, les phosphates solubles dans l'eau et les agents séquestrants du type acide aminopolycarboxylique; l'agent de tonicité est choisi parmi les halogénures, les phosphates, les hydrogénéophosphates et les borates de métaux alcalins; l'agent accroissant la viscosité est choisi parmi l'alcool polyvinylique et l'hydroxyéthylcellulose; le tampon est choisi parmi les phosphates de métaux alcalins, les borates de métaux alcalins et les pyruvates de métaux alcalins, isolément ou en combinaison avec leurs acides respectifs.

7. Un procédé pour désinfecter un article stable au peroxyde d'hydrogène, qui consiste à mettre cet article en contact avec une solution de peroxyde d'hydrogène dont la préparation est décrite dans la revendication 1.

8. Le procédé de la revendication 7, dans lequel cet article consiste en une matière polymère pour lentilles de contact.

9. Le procédé de la revendication 8, dans lequel la matière polymère pour lentilles de contact est choisie parmi les matières polymères pour lentilles de contact molles et les matières polymères perméables aux gaz pour lentilles de contact rigides.

10. Le procédé de la revendication 8, dans lequel l'article est une lentille de contact.

11. Le procédé de désinfection d'une lentille de contact polymère consistant à mettre cette lentille en contact avec une solution de peroxyde d'hydrogène stabilisée selon revendication 4.

12. Le procédé de la revendication 11, utilisant une solution selon revendication 5.

13. Le procédé de la revendication 12, utilisant une solution selon revendication 6.

14. Le procédé de la revendication 11, dans lequel le pH de la solution de peroxyde d'hydrogène stabilisée

est d'environ 5,5 à environ 8,0.

15. Le procédé de la revendication 11, dans lequel la solution de peroxyde d'hydrogène stabilisée a une tonicité d'environ 390 à 1350 milliosmoles avant décomposition du peroxyde d'hydrogène et d'environ 250 milliosmoles à environ 350 milliosmoles après décomposition complète du peroxyde d'hydrogène.

5 16. Le procédé de la revendication 11, dans lequel la solution de peroxyde d'hydrogène stabilisée a une viscosité allant jusqu'à 1 000 cps.

17. Le procédé de la revendication 11, dans lequel le contact dure pendant au moins 10 minutes.

18. Le procédé de la revendication 17, comprenant en outre la décomposition du peroxyde d'hydrogène après le contact.

10 19. Le procédé de la revendication 18, dans lequel la solution de peroxyde d'hydrogène stabilisée, après la décomposition, est pratiquement isotonique.

20. Le procédé de la revendication 18, dans lequel la décomposition est réalisée à l'aide d'un agent acceptable pour l'usage ophtalmologique.

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